Sotera WIRELESS

510(k) Summary

AUG 15 2012

Date prepared	May 30, 2012
Name	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.373.4841; F. 858.427.4639
Contact person	Eben Gordon Senior Director, Regulatory
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Classification name	Cardiac monitor (including cardiotachometer and rate alarm)
Classification regulation	21 CFR 870.2300
Product code	MWI, DRT, DXN, DQA and FLL
Predicate device	ViSi Mobile Monitoring System (K112478) Propaq LT VSM, Model 802 Series (K033378) Micropaq VSM, Models 402, 404 (K002725) Acuity Central Monitoring Station Predicate (K022453)
Description	The ViSi Mobile Monitoring System is a lightweight, portable patient vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is body-worn and designed to continuously measure ECG, heart rate, SpO2, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. NIBP can be measured as a onetime measurement, or it can be measured automatically at predefined intervals
Indications for use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin, pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments. The ViSi Mobile Monitoring System may be used as standalone devices or networked to a central station through wireless 802.11 communication.
Summary of substantial equivalence	The ViSi System has been tested and complies with recognized performance, safety, and electromagnetic compatibility standards for medical devices. The verification and validation activities performed based

the FDA's draft guidance on **Radio-Frequency Wireless Technology in Medical Devices** provides assurance of a more reliable wireless connection. These results demonstrate that the ViSi System is safe, as effective, and based on the similarities with the predicate devices, substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 15 2012

Sotera Wireless, Inc
c/o Mr. Mark Job
Third Party Reviewer: Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K122036
Trade Name: ViSi Mobile Monitoring System
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor Including Cardiotachometer and Rate Alarm
Regulatory Class: II (two)
Product Code: MWI, DRT, DXN, DQA, FLL
Dated: July 30, 2012
Received: July 31, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE

510(k) Number (if known): K122036

Device Name: _____ ViSi Mobile Monitoring System _____

Indications for Use:

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to central station through wireless 802.11 communication.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122036